The Analgesic Efficacy of Ultrasound-guided Transversus Abdominis Plane (TAP) Block Combined With Oral Multimodal Analgesia In Comparison With Oral Multimodal Analgesia After Caesarean Delivery: A Randomized Controlled Trial

YANG YU
University of Hong Kong-Shenzhen Hospital https://orcid.org/0000-0001-7523-6374
Shenshan GAO
University of Hong Kong-Shenzhen Hospital
Vivian Manying YUEN
HongKong Children's Hospital
Wai Siu CHOI
"University of HongKong
Xuebing XU (xuxb@hku-szh.org)
University of Hong Kong - Shenzhen Hospital https://orcid.org/0000-0002-5042-0578

Research article

Keywords: transversus abdominis plane block, oral analgesics, caesarean delivery

Posted Date: November 3rd, 2020

DOI: https://doi.org/10.21203/rs.3.rs-50223/v2

Version of Record: A version of this preprint was published on January 7th, 2021. See the published version at https://doi.org/10.1186/s12871-020-01223-3.

Abstract

Background: The transversus abdominis plane (TAP) block is used increasingly in parturients after caesarean delivery. This is a randomized controlled trial to evaluate the effectiveness of bilateral single-shot TAP blocks in patients who received multimodal oral analgesia for postoperative pain relief.

Methods: Parturients who were scheduled for elective caesarean delivery under spinal anaesthesia were recruited and randomized to receive bilateral single-shot of TAP blocks or placebo in addition to multimodal oral analgesia which consisted of regular tramadol, celecoxib and paracetamol, with oral oxycodone used as rescue for breakthrough pain. Only parturients in TAP group would receive the TAP blocks with an injection of 15ml (0.25%) ropivacaine on each side under aseptic techniques. All the parturients were evaluated for pain or related complications in the first 24 hours after surgery. Primary outcome is the percentage of parturients who required oxycodone as rescue analgesia.

Results: Eighty and seventy-nine parturients were allocated to TAP and placebo group respectively. Nine out of 79 (11.4%) parturients in TAP group and fifteen out of 73 (20.5%) parturients in placebo group required oxycodone for breakthrough pain, P = 0.122.

Conclusions: Bilateral single-shot of TAP blocks confer little additional benefit when multimodal oral analgesic regimen is used for pain control after caesarean section under spinal anaesthesia.

Trial registration:

Clinical Trial Registry of China (http://www.chictr.org.cn, ChiCTR-INR-16010130). Retrospective registered on Dec 12, 2016

Background

With the availability of ultrasound machine, transversus abdominis plane (TAP) block may be easily performed after caesarean section for postoperative analgesia. It was shown to be effective and reduce intravenous morphine consumption in patients who used patient-controlled intravenous morphine analgesia for post-caesarean pain relief.[1] Previous systemic reviews and meta-analyses have revealed that it is only effective after caesarean delivery provides effective analgesia when spinal morphine is not used,[2,3] therefore TAP block offer little additional benefits when patients have intrathecal morphine administered. Although intrathecal morphine is the best option for post caesarean pain relief,[4] preservative free morphine is not available in our center and in most part of China. The routine post-caesarean analgesia in our center consists of multimodal oral analgesia including regular tramadol (SR 100 mg BID for 2 days), cyclooxygenase-2 inhibitor (parecoxib 200 mg BID for 3 days) and paracetamol (1000 mg QID for 4 days), with oral oxycodone (10 mg) as rescue pain relief. Our quality assurance exercise revealed satisfactory pain control with this regime, and the proportion of patients who required oxycodone rescue range from 15–20% and less than 1% of patient would need intravenous morphine as rescue analgesia. Since TAP block has been shown significantly reduce intravenous morphine

consumption in the first 24 hours after caesarean section, we conducted this double-blind randomized controlled trial to test the hypothesis that TAP block would further improve post-caesarean analgesia in patients who have multi-modal oral analgesia.

Methods

The study was carried out in a tertiary care public hospital in Shenzhen, China. It was approved by the Hospital Institutional Review Board (szkcw201628) and registered with the Clinical Trial Registry of China (ChCTR-INR-16010130). After patient informed consent was obtained, the parturients scheduled for elective caesarean delivery under spinal anaesthesia were enrolled in the study. Spinal anesthesia was performed in lateral position at the L2/3 or L3/4 interspace with 0.5% hyperbaric bupivacaine 10mg (2ml) combined with fentanyl 15μg (0.3ml) in both groups. Inclusion criteria were American Society of Anaesthesiologists physical status I or II parturients, scheduled for elective caesarean delivery under spinal anesthesia. Exclusion criteria included body mass index more than 35kg/m^2, major systemic disease, chronic pain disorders, neurological disorders, abuse of drugs or alcohol, and allergies to any medication included in the study protocol and inability to comprehend or use the visual rating pain scoring system.

An independent statistician prepared a randomization list with block of group allocation was kept in concealed opaque envelops. Attending anaesthetists would disclose group assignment at the start of surgery ,and prepare for the TAP blocks if necessary. In order to ensure the recruited parturients who had spinal anaesthesia were blind from group allocation and avoid sham block, the surgical drape which block parturients' view of her surgical site was kept after surgery. After a wound was covered with dressing, an ultrasound-guided bilateral single-shot of TAP blocks were performed by the attending anaesthetists who are experienced with this technique before conducting the investigation. A linear 13- to 6-MHz ultrasound probe (Sonosite ^{TM}, Bothell, Washington) was placed transversely on the anterolateral abdominal wall between the iliac crest and costal margin. The three layers of muscles - the external oblique, the internal oblique, and the transversus abdominis - were identified. Only parturients who were allocated to have TAP blocks would have injection of local anaesthesia under aseptic techniques. A 22-gauge, 90-mm SonoPlex Stim needle (Pajunk Medizintechnik, Geisingen, Germany), attached with flexible tubing to a syringe filled with 0.9% normal saline, was introduced through the skin anteriorly in the plane of the ultrasound beam, and advanced into the fascial plane between the internal oblique muscle and transversus abdominis muscles. Ropivacaine（Naropin, Astrazeneca AB. Sweden)15ml (0.25%) was injected on each side of abdominal wall for the TAP blocks. Local anaesthetic solution was injected in 5 ml increments after aspiration. After each 5 ml bolus, patients were monitored for an increase in heart rate or signs of local anesthetic toxicity such as tinnitus, perioral numbness, metallic taste in mouth, slurring of speech, and mental status changes. Since the parturients who had effective spinal block would not feel the needle injection of TAP blocks, it was possible to blind the participants from group allocation as ultrasound scan would be performed even if TAP blocks were not administered.

All recruited patients had intravenous parecoxib 40mg before the end of operation. They were also prescribed multimodal oral analgesics postoperatively, and this included slow release tramadol 100mg twice a day for the first two days, celecoxib 200mg twice a day for three days, and paracetamol 1000mg four times a day for four days. Oxycodone 10mg for once as PRN was prescribed and used when necessary.

Participants were given instruction to fill in a survey for postoperative pain control. The numeric rating scale (NRS) for pain and satisfaction scale was explained. NRS consist scores of 0 to 10, with 0 equals to no pain and 10 equals to the worst pain. A scale of 5 were used as a satisfactionion score, with 1 equals to “very unsatisfactory” and 5 equals to “very satisfactory” with pain relief. The participants were asked to record the NRS at rest, with movement, and with uterine massage and the satisfaction score at 2 hours, 4 hours, 6 hours and 12 hours after completion of surgery. In addition, they were asked to record if there was an episode of nausea and vomiting. The parturients would also record if oxycodone or uterotonic was used in the first 24 hours. Moreover, they would also record if there was any instance of pain when NRS was greater than 6 in the first 24 hours. The survey was collected by pain nurse during follow up on day 1 after operation.

Primary outcome is the percentage of parturients who required oxycodone as rescue analgesia. Secondary outcomes include the NRS at rest, NRS with movement and NRS during uterine massage, patient satisfaction score, the percentage of parturients who experienced pain with NRS > 6 during the first 24 hours after surgery, and the incidence of nausea and vomiting. According to our record of routine postoperative visit, approximately 20% of our patients required oxycodone as rescue pain relief. If TAP blocks would decrease the requirement of oxycodone from 20% to 5%, 73 parturients per group is required for 80% power with 5% type 1 error.

Parametric primary and secondary outcomes are presented as mean (SD) or number (percentage) and were compared by t-test or Chi-square test. Non-parametric data are presented as median (IQR [range]) and compared by Mann-Whitney U test. The area under the curve (AUC) for pain scores and satisfaction scores were derived using the trapezoidal rule. The mean AUC of pain scores and satisfaction scores were presented as mean (SD) and compared using t-test. A P value <0.05 was considered significance. Data were analysed using SPSS (version 21.0; SPSS Inc., Chicago, IL, USA).

Results

One hundred and sixty-three patients were approached, and 159 patients consented to take part in this study between April and September in 2016. Eighty parturients received TAP blocks and seventy-nine were allocated to placebo group (Fig.1). One patient from the TAP group and five patients from placebo group were excluded because either the patents lost the record sheets or forgot to record any data. As a result, primary outcome was available from 79 and 73 parturients in TAP and placebo group respectively. In all patents in TAP group, the transversus abdominis neurofascial plane was localized by ultrasound easily, and the block was performed without complication. Demographic information is presented in

Table 1. Nine out of 79 (11.4%) and fifteen out of 73 (20.5%) parturients required oxycodone for breakthrough pain (P = 0.122 Table 3). The AUC of NRS for pain at rest (Fig. 2 and during movement (Fig. 3) for the first 24 hours was not different between the two groups (P = 0.87 and P = 0.95 respectively, Table 2). The AUC of NRS for pain during uterine massage (Fig.4) for the first 12 hours was also not different between the two groups (P = 0.66, Table 2). The AUC of patient satisfaction score for the first 12 hours was not different between the two groups (P = 0.58, Table 2).There was no difference in incidence of nausea and vomiting between the two groups and a similar proportion of patients required uterotonic for controling of bleeding (Table 3). Sixty-eight patients in TAP group and sixty-two patients in placebo group were analyzed for the patients experienced severe pain (with NRS > 6 at any time point) because some patients failed to return the postop pain survey. Thirty-two of 68 (47.1%) patients in TAP group experienced severe pain (with NRS > 6 at any time point) versus thirty-nine of 62(62.9%) patients in the placebo group (P = 0.07) during the first 24 hours post-operatively (Table 3).

Discussion

Our study demonstrates that TAP blocks are not associated with reducing the use of rescue oxycodone. The analgesic efficacy of TAP blocks for caesarean delivery remains controversial. TAP blocks have been shown to be inferior to spinal morphine for post-caesarean delivery pain,[4,5] and they are ineffective when spinal morphine was used,[3,6,7] it is associated with effective analgesia in patients after caesarean delivery when spinal morphine is not used.[2,3] Although we have revealed in this study that bilateral single-shot of TAP blocks confer little additional benefit when multimodal oral analgesic regimen inclusive of tramadol, celecoxib and paracetamol is used, with the advancement of ultrasound technology, TAP blocks become technically easier and safer to perform,[8] ultrasound-guided nerve blocks offer the advantage of real-time imaging of the needle trajectory and injection spread, which may improve both safety and block effectiveness. This technique would be up to the individual anaesthesiologist or department to decide whether it is cost effective and worthwhile additional procedure in their own settings.

The advantage of multimodal oral analgesia includes ease of administration with no device requested for drug administration. This would facilitate early mobilization after surgery. Recently the U.S. Food and Drug Administration has issued warning to mothers that breastfeeding is not recommended when taking tramadol due to the risk of serious adverse reactions in breastfed infants.[9] In a recent review on the tramadol use in breastfeeding mother and new-born, it is revealed that there has been no reported deaths of breastfed newborns in association with maternal tramadol use.[10]

Since patients and pain nurse who performed the postoperative visit were blind to group assignment, this allow us to evaluate the effectiveness of TAP block without bias. Moreover, all anaesthetists who performed the block were experienced in doing TAP block. After all, with the use of ultrasound, TAP block is easily performed. Since the postoperative pain score was recorded by the patients themselves before our routine postoperative pain round, this would also further reduce the possibility of bias on pain

assessment. However, it is also difficult to exclude failed TAP block which serves as a cause for analgesia inefficacy due to the fact that residual sensory block from spinal maintains.

Conclusions

In conclusion, this double blinded randomized controlled trial revealed that bilateral single-shot TAP blocks confer little additional benefit when multimodal oral analgesic regimen is used for post caesarean section.

Abbreviations

TAP: transversus abdominis plane; NRS: numeric rating scale; AUC: area under the curve

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of University of Hong Kong - Shenzhen Hospital (szkcw201628) on April 8, 2016, and registered with the Clinical Trial Registry of China (ChiCTR-INR-16010130). We have obtained written informed consents from all of the participants in the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author for reasonable request. The datasets used are also available from Clinical Trial Registry of China. (http://www.chictr.org.cn/hvshowproject.aspx?id=11718)

Competing interests

The authors declare that they have no competing interests.

Funding

None

Authors' contributions

VMYY, YY, XBX conceived the study.

YY, SSG, XBX,VMYY performed experiments.

SW C, VMYY, YY and XBX analysed the data and prepared the manuscript.

SWC, VMYYuen, YY, SSG, XBX critically reviewed the manuscript.

All authors have read and approved the final manuscript.

Acknowledgements

Not applicable

References

1. McDonnell JG, Curley G, Carney J, Benton A, Costello J, Maharaj CH, Laffey JG. The analgesic efficacy of transversus abdominis plane block after cesarean delivery: a randomized controlled trial. Anesth Analg 2008; 106: 186-91
2. Abdallah FW, Halpern SH, Margarido CB. Transversus abdominis plane block for postoperative analgesia after Caesarean delivery performed under spinal anaesthesia? A systematic review and meta-analysis. Br J Anaesth 2012; 109: 679-87
3. Mishriky BM, George RB, Habib AS. Transversus abdominis plane block for analgesia after Cesarean delivery: a systematic review and meta-analysis. Can J Anaesth 2012; 59: 766-78
4. Kanazi GE, Aouad MT, Abdallah FW, Khatib MI, Adham AM, Harfoush DW, Siddik-Sayyid SM. The analgesic efficacy of subarachnoid morphine in comparison with ultrasound-guided transversus abdominis plane block after cesarean delivery: a randomized controlled trial. Anesth Analg 2010; 111: 475-81
5. Loane H, Preston R, Douglas MJ, Massey S, Papsdorf M, Tyler J. A randomized controlled trial comparing intrathecal morphine with transversus abdominis plane block for post-cesarean delivery analgesia. Int J Obstet Anesth 2012; 21: 112-8
6. Costello JF, Moore AR, Wieczorek PM, Macarthur AJ, Balki M, Carvalho JC. The transversus abdominis plane block, when used as part of a multimodal regimen inclusive of intrathecal morphine, does not improve analgesia after cesarean delivery. Reg Anesth Pain Med 2009; 34: 586-9
7. McMorrow RC, Ni Mhuircheartaigh RJ, Ahmed KA, Aslani A, Ng SC, Conrick-Martin I, Dowling JJ, Gaffney A, Loughrey JP, McCaul CL. Comparison of transversus abdominis plane block vs spinal morphine for pain relief after Caesarean section. Br J Anaesth 2011; 106: 706-12
8. McDonnell NJ, Paech MJ. The transversus abdominis plane block and post-caesarean analgesia: are we any closer to defining its role? Int J Obstet Anesth 2012; 21: 109-11
9. U.S. Food and Drug Association. FDA drug safety communication: FDA restricts use of prescription codeine paina nd cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Updated 2017. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm

10. Palmer GM, Anderson BJ, Linscott DK, Paech MJ, Allegaert K. Tramadol, breast feeding and safety in the newborn. Arch Dis Child 2018; 103: 1110-1113

Figures

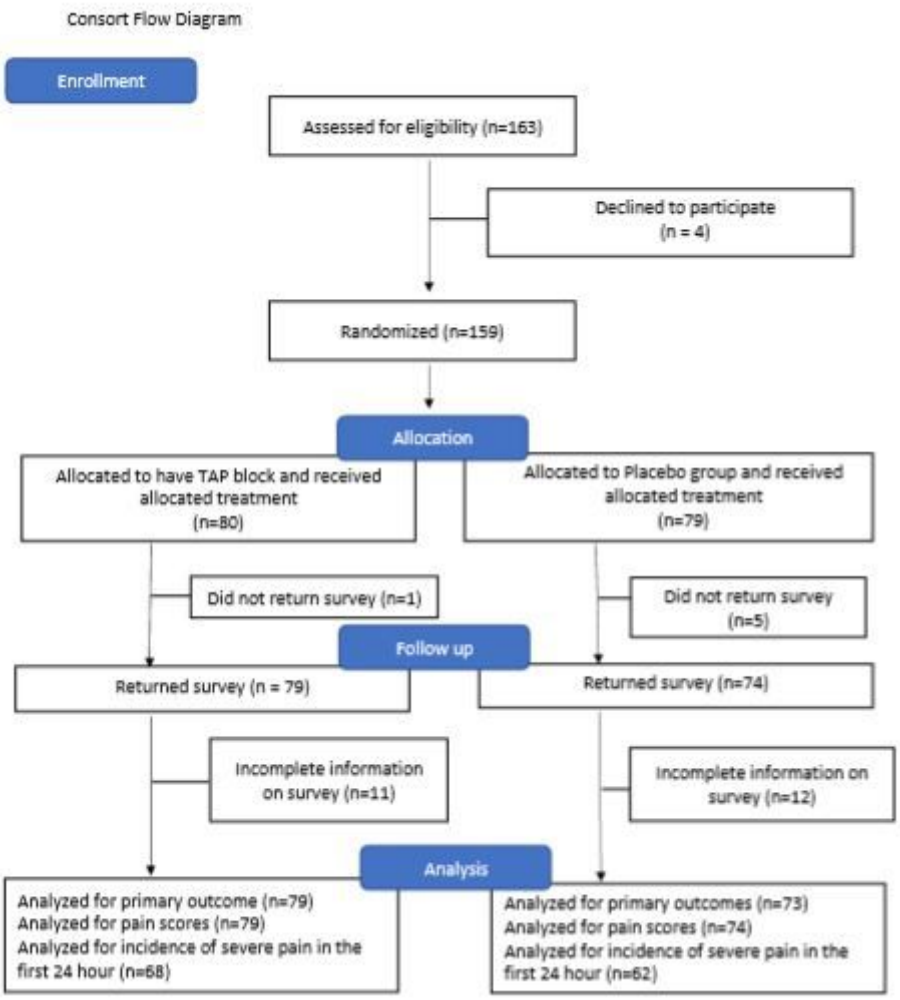

Figure 1

Consort flow diagram. Patients were excluded because of incompleting information.

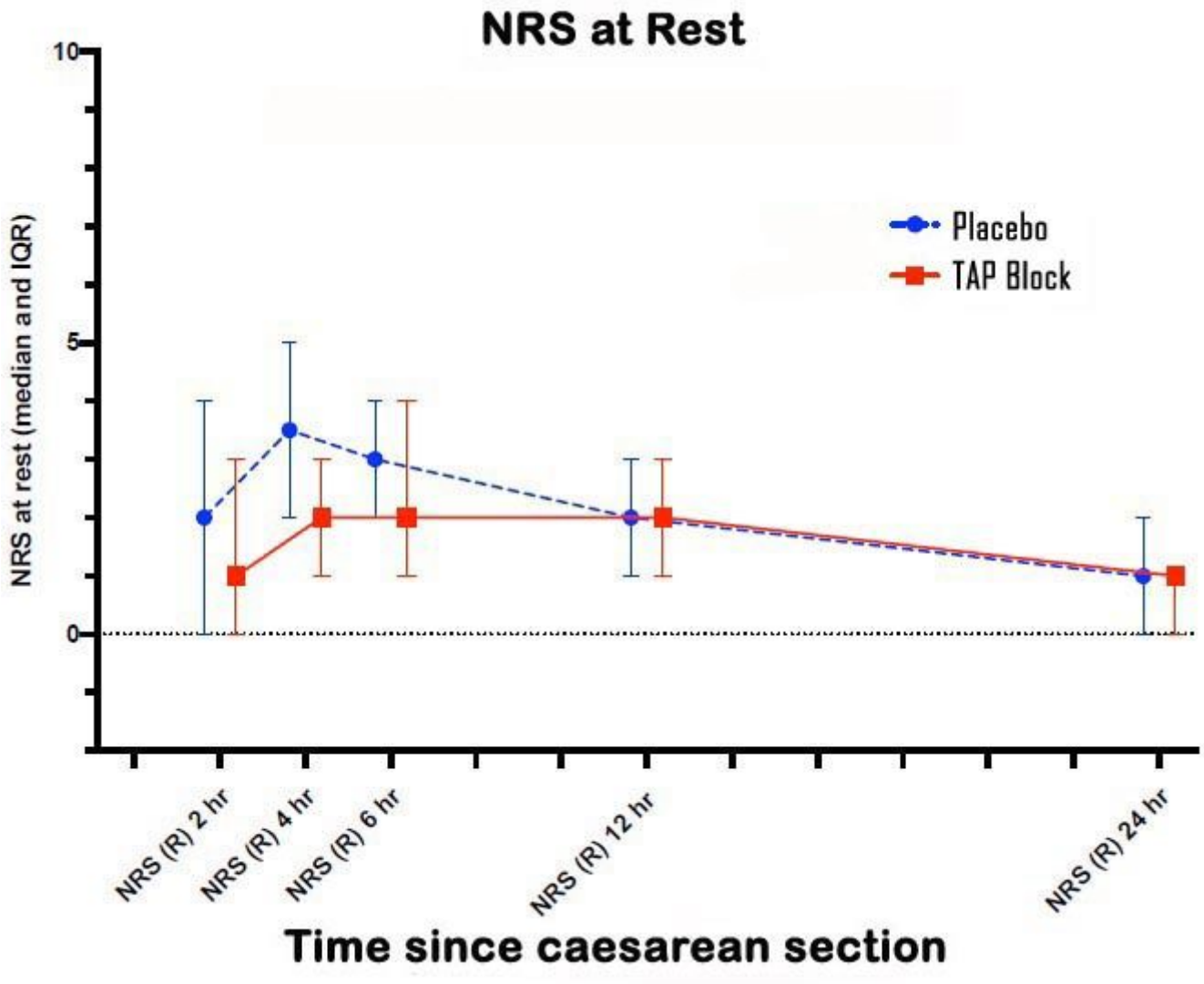

Figure 2

NRS at rest. The median (IQR) pain score in numeric rating scale (NRS) at rest in the placebo group (blue circle) and the TAP group (red square) over the first 24 hours after Caesarean section.

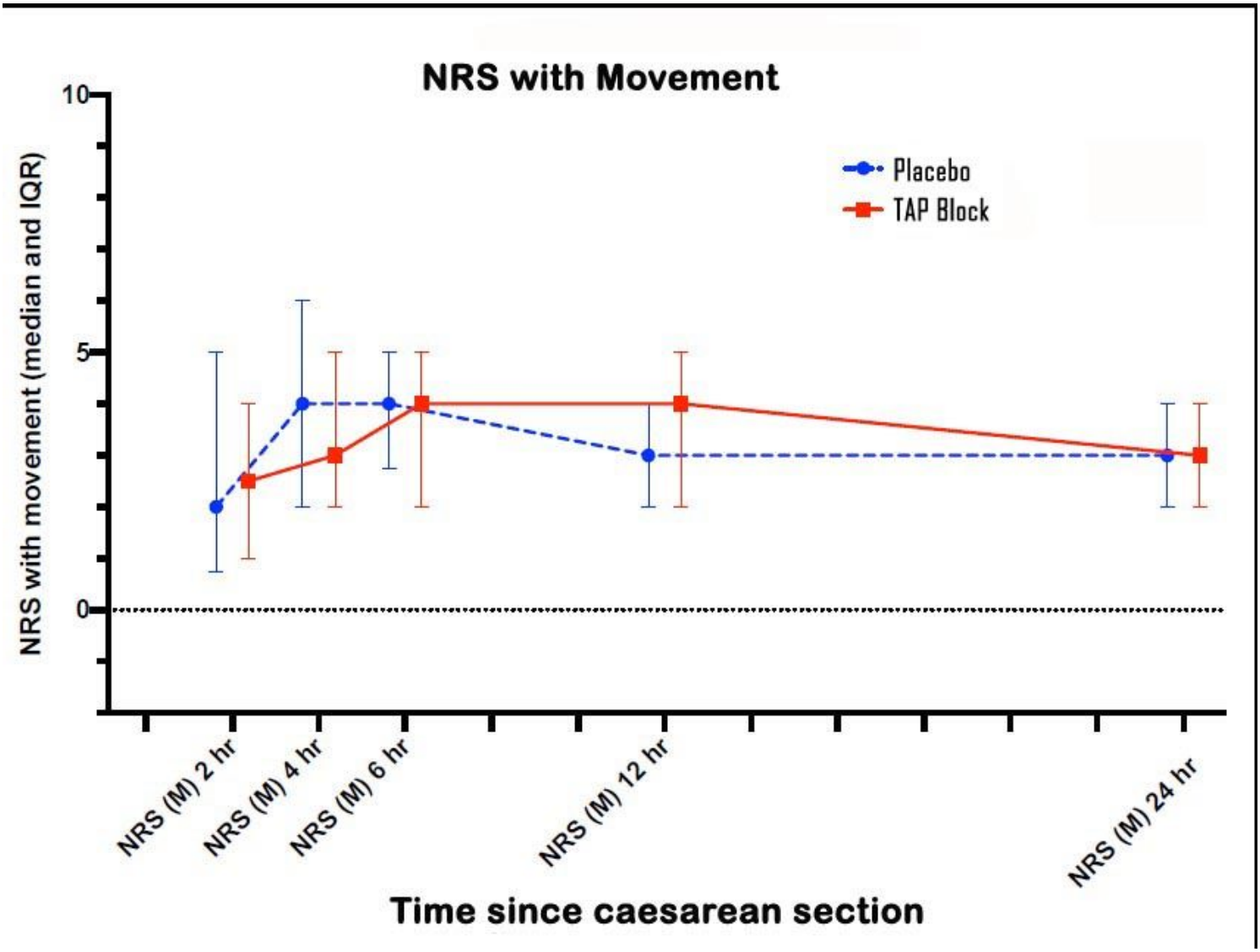

Figure 3

NRS with movement. The median (IQR) pain score in numeric rating scale (NRS) with movement in the placebo group (blue circle) and the TAP group (red square) over the first 24 hours after Caesarean section.

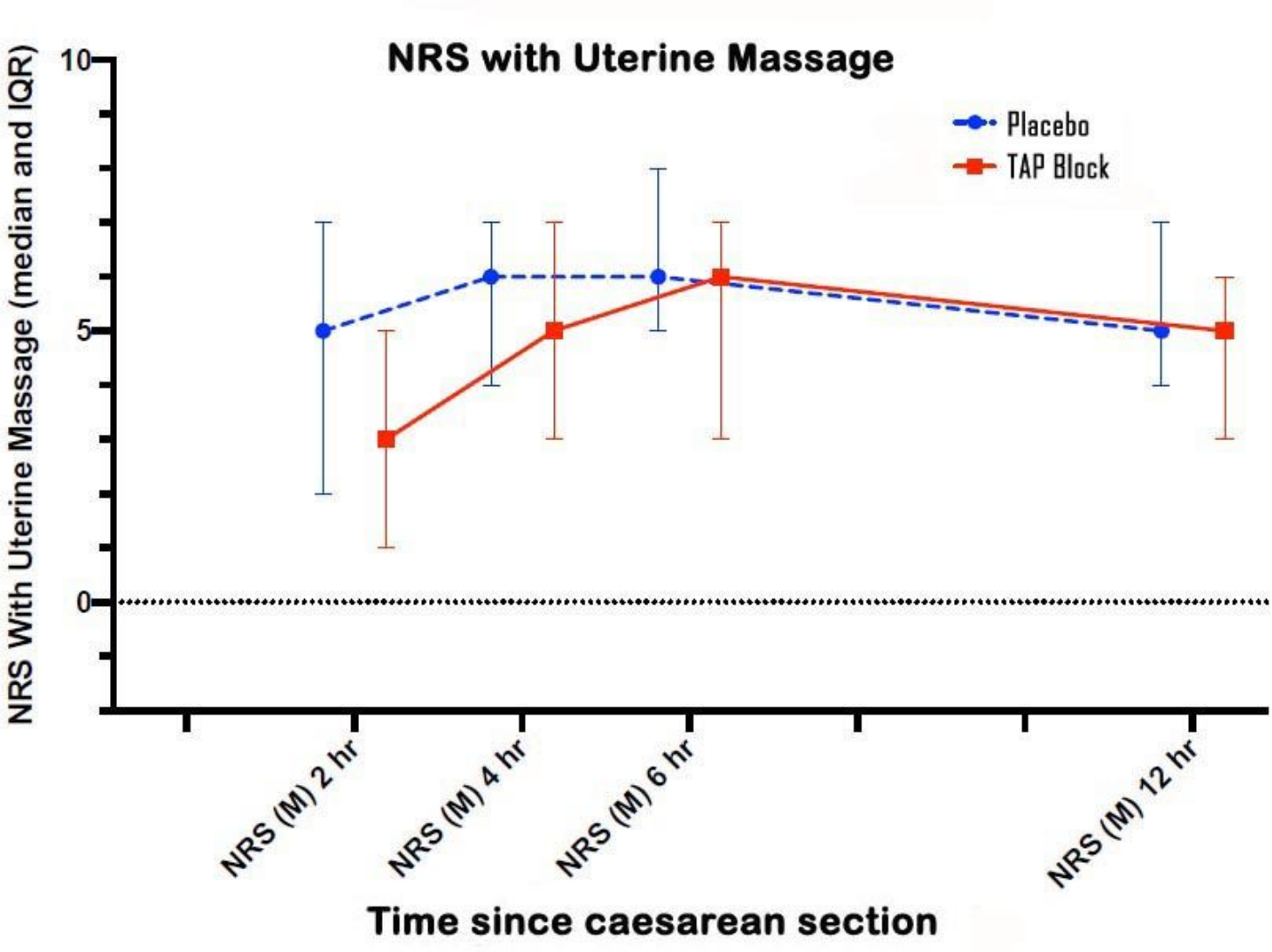

Figure 4

NRS Uterine massage. The median (IQR) pain score in numeric rating scale (NRS) with uterine massage in the placebo group (blue circle) and the TAP group (red square) over the first 12 hours after Caesarean section.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORTChecklistR2.doc